Applicant: Bhamare et al.

Application No.: 10/568,325

IN THE CLAIMS

(Currently amended) A pharmaceutical composition for controlled

drug delivery comprising a cephalosporin antibiotic and a combination of at least

two carbomers.

2. (Original) The composition of claim 1 wherein said cephalosporin

antibiotic is selected from cefdinir, cefditoren pivoxil, cefepime, cefixime,

cefoperazone, cefotetan, cefpodoxime paroxetil, cefprozil, cefazidine, ceftibuten,

ceftriaxone, cefuroxime axetil, cephalexin, cefaclor, cefadroxil, cefamandole,

cefoxitin, cefalothin, moxalactum, cefapirin, ceftizoxime, cefonicid, cephadrine,

loracarbef, cefetamet and pharmaceutically acceptable hydrates, salts or esters

thereof

3. (Original) The composition of claim 2 wherein said cephalosporin is

 $cefprozil\ or\ its\ pharmaceutical\ acceptable\ hydrates,\ salts\ or\ esters.$

(Original) The composition of claim 3 wherein said cefprozil or their

pharmaceutical acceptable hydrates, salts or esters may be present in an amount

from 100 mg. to 1000 mg.

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 (Currently amended) The composition of claim 3 wherein said cefprozil or their pharmaceutical acceptable hydrates, salts or ester may be present

from about 30-90% w/w of the formulation

6. (Currently amended) The composition of claim 1 wherein said

carbomers are a mixture of Carbopol 971P® and Carbopol 974P®.

7. (Original) The composition of claim 1 wherein said carbomers

comprise about 0.1% to 50% by weight of the controlled release composition.

8. (Original) The composition of claim 7 wherein said carbomers are

present at a concentration from about 5% to about 50% comprising of Carbopol 971P

in an amount from about 0.1% to about 20% by weight and Carbopol 974P in an

amount from about 0.1% to about 30% by weight of controlled release composition.

9. (Currently amended) The Composition of claim 1 which further

comprises other pharmaceutically acceptable excipients selected amongst water-

soluble or water dispersible diluents and lubricants.

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10. (Original) The composition of claim 9 wherein said water-soluble

diluent is selected from lactose, mannitol, glucose, sorbitol, maltose, dextrates,

dextrins and the like.

11. (Currently Amended) The composition of claim 10 wherein said

water-soluble diluent is lactose from about 5% to about 20% by weight of the

formulation.

12. (Cancelled)

13. (Original) The composition of claim 9 wherein said water dispersible

diluent is selected from amongst microcystalline cellulose, starch, pre-gelantinized

starch, magnesium aluminum silicates and the like.

14. (Currently Amended) The composition of claim 13 wherein said

water dispersible diluent is microcrystalline cellulose from about 5% to about 20%

by weight of the formulation.

15. (Cancelled)

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16. (Original) The composition of claim 9 wherein said pharmaceutical

excipient is either one or a combination of lubricants at a concentration in the range

of about 0.2% to 5% by weight of the composition.

17. (Original) The composition of claim 9 wherein said lubricant is

selected from talc, stearic acid, magnesium stearate, colloidal silicon dioxide,

calcium stearate, zinc stearate, hydrogenated vegetable oil and the like.

18. (Cancelled)

19. (Original) The process for the preparation of the pharmaceutical

composition comprising mixing together, a cephalosporin antibiotic or their

pharmaceutically acceptable hydrates, salts or esters; with combination of

carbomers and optionally, with one or more water soluble or water dispersible

diluents and lubricants to form the blend, and compressing the blend into tablets.

20. (Original) The process of claim 19 wherein the blend may be

compacted into granules.

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21. (Original) A controlled release composition of cephalosporin

antibiotic comprising a pharmaceutically effective amount of cephalosporin

antibiotic, combination of carbomers, a water-soluble and/or water dispersible

diluent and pharmaceutically acceptable tablet excipients for controlling the release

of cephalosporin antibiotic.

22. (Original) A controlled release composition comprising a

cephalosporin antibiotic and a release controlling polymer wherein the Cmax is

substantially the same as that of a single dose of an immediate release formulation.

23. (Original) A controlled release composition of claim 22 wherein the

cephalosporin antibiotic is cefprozil.

24. (Original) A controlled release composition comprising a

cephalosporin antibiotic and a release-controlling polymer wherein the T > MIC at

0.25 mcg/ml was achieved for about 75% of the dosing interval and T > MIC of 2

mcg/ml was achieved for almost 49% of the dosing interval.

25. (Original) A controlled release composition of claim 24 wherein the

cephalosporin antibiotic is cefprozil.

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26. (Currently amended) <u>A</u> The controlled release composition of claim

21 further comprising from about 30 - 90 % w/w of cefprozil and from about 0.1-50 %

by weight of one or a mixture of carbomers and optionally one or more

pharmaceutically acceptable excipients selected from amongst diluents and

lubricants.

27. (Cancelled)

28. (New) The composition of claim 11 wherein said lactose amounts from

about 5% to about 20% by weight of the formulation.

29. (New) The composition of claim 14 wherein said microcrystalline

cellulose amounts from about 5% to about 20% by weight of the formulation.

30. (New) The composition of claim 17 wherein said lubricant is

preferably selected from talc, stearic acid, magnesium stearate and colloidal silicon

dioxide.

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31. (New) A controlled release composition of claim 26 preferably comprising from about 40-80% w/w of cefprozil and from about 0.1-40% w/w of one or a mixture of carbomers and optionally one or more pharmaceutically acceptable excipients selected from amongst diluents and lubricants.